

05-1507

WAF

PTO/SB/21 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/777,018
Filing Date	February 5, 2001
First Named Inventor	Hastings, et al.
Art Unit	3771
Examiner Name	Adam Curtis Brandt
Total Number of Pages in This Submission	32
Attorney Docket Number	5236-000215

ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Technology Center (TC)
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Check for \$500
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	Copy of Final Office Action
<input type="checkbox"/> Certified Copy of Priority Document(s)		Return Postcard
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

Remarks

The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Harness, Dickey & Pierce, P.L.C.		
Signature			
Printed name	Kevin Pumm		
Date	May 14, 2007	Reg. No.	49,046

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Kevin Pumm	Express Mail Label No.	EV 844119685 US
Signature		Date	May 14, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

EV 844119685 US

FEE TRANSMITTAL
for FY 2007

Effective 2/1/2006. Patent fees are subject to annual revision.

Patent claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 500**Complete if Known**

Application Number	09/777,018
Filing Date	February 5, 2001
First Named Inventor	Hastings, et al.
Examiner Name	Adam Curtis Brandt
Art Unit	3771
Attorney Docket No.	5236-000215

METHOD OF PAYMENT (check all that apply)
☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None
☒ Deposit Account:
 Deposit Account Number
08-0750

 Deposit Account Name
Harness, Dickey & Pierce, PLC

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.
FEE CALCULATION**1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1011	300	2011	150	Utility filing fee	
1012	200	2012	100	Design filing fee	
1013	200	2013	100	Plant filing fee	
1014	300	2014	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	
SUBTOTAL (1)					(\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		-20 **	=	0	X	Fee from below	=	0	Fee Paid
Independent Claims		-3 **	=	0	X		=	0	
Multiple Dependent							=	0	

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	50	2202	25	Claims in excess of 20	
1201	200	2201	100	Independent claims in excess of 3	
1203	360	2203	180	Multiple dependent claim, if not paid	
1204	200	2204	100	** Reissue independent claims over original patent	
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	500
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive - unavoidable	
1453	1500	2453	750	Petition to revive - unintentional	
1462	400	1462	400	Petition fee under 37 CFR 1.17(f)	
1463	200	1463	200	Petition fee under 37 CFR 1.17(g)	
1464	130	1464	130	Petition fee under 37 CFR 1.17(h)	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** (\$500)**4. SEARCH/EXAMINATION FEES**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1111	500	2111	250	Utility Search Fee	
1112	100	2112	50	Design Search Fee	
1113	300	2113	150	Plant Search Fee	
1114	500	2114	250	Reissue Search Fee	
1311	200	2311	100	Utility Examination Fee	
1312	130	2312	65	Design Examination Fee	
1313	160	2313	80	Plant Examination Fee	
1314	600	2314	300	Reissue Examination Fee	
SUBTOTAL (4)					(\$) 0

SUBMITTED BY**Complete (if applicable)**

Name (Print/Type)	Kevin Pumm	Registration No. (Attorney/Agent)	49,046	Telephone	314-726-7500
Signature	<i>Kevin Pumm</i>	Date	May 14, 2007		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

EV 844119685 US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/777,018
Filing Date: February 5, 2001
Applicant: Hastings et al.
Group Art Unit: 3771
Examiner: Adam Curtis Brandt
Title: Magnetically Guided Atherectomy
Attorney Docket: 5236-000215

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF
UNDER 37 C.F.R. § 41.37

Sir:

The Notice of Appeal in this Application was filed on March 13, 2007. This brief is submitted with the fee required under 37 C.F.R. §1.17(f).

05/16/2007 SSITHIB1 00000026 09777018

01 FC:1402

500.00 DP

Serial No.:09/777,018

EV 844119685 US

Page 1 of 18

APPELLANT'S BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 41.37, Appellants submit their Brief on Appeal, as follows:

REAL PARTY IN INTEREST – UNDER 37 C.F.R. § 41.37(c)(1)(i)

The real parties in interest in this appeal are Stereotaxis, Inc., a Delaware corporation, having a place of business at 4320 Forest Park Avenue, Suite 100, St. Louis, MO 63108, by virtue of an assignment to Stereotaxis recorded at Reel 011985, Frame 0358.

RELATED APPEALS & INTERFERENCES - UNDER 37 C.F.R. § 41.37(c)(1)(ii)

To the best of Appellants' knowledge, no other appeals or interferences are pending which will directly affect, be directly affected by or have a bearing on the Board's decision in the present pending appeal.

STATUS OF THE CLAIMS – UNDER 37 C.F.R. § 41.37(c)(1)(iii)

On March 13, 2007, Appellants appealed from the final rejection of Claims 34-44.

- A copy of the claims presently being appealed (i.e., Claims 34-44) is provided in the attached Claims Appendix.
- A copy of the Final Office Action mailed November 13, 2006 placing claims 34-44 under final rejection is provided in the attached Evidence appendix.

STATUS OF AMENDMENTS – UNDER 37 C.F.R. § 41.37(c)(1)(iv)

A Final Office Action was mailed November 13, 2006, placing claims 34-44 under final rejection. An Amendment After Final was submitted on November 28, 2006, in response to which an Advisory Action was issued on January 3, 2007 that denied entry of the Amendment After Final. A Notice of Appeal was filed on March 13, 2007.

SUMMARY OF THE CLAIMED SUBJECT MATTER – UNDER 37 C.F.R. § 41.37(c)(1)(v)

Independent Claim 34

An atherectomy device comprising:

a catheter having a proximal and a distal end and a lumen therebetween;

a support structure in the lumen adjacent the distal end;

one or more optical conduits in the catheter, each having a distal end supported by the support structure;

one or more magnetic members disposed in the distal end of the catheter whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field; and

wherein the one or more optical conduit in the distal end are rotatable within the support structure.

With regard to independent claim 34, the elements of this claim are disclosed in paragraphs 13, 49 and 88 of the present application. Paragraph 88

of the present application discloses a catheter having "a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheromatous material distal to the tool. The tool 810 also includes a passage 818." Paragraphs 13 and 49 further clarify that "open" lumens of the device can be used with optical coherence tomographic, or laser based imaging systems. Paragraph 88 clarifies that the catheter has a distal end structure 812, and paragraph 89 clarifies that the catheter has magnet members at the distal end.

Independent Claim 35

An atherectomy device comprising:

a catheter having a proximal and a distal end and a lumen therebetween;

a support structure in the lumen adjacent the distal end;

one or more optical conduits in the catheter, each having a distal end supported by the support structure;

one or more magnet members disposed in the distal end of the catheter that orient the distal end to align relative to an applied magnetic field, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field; and

wherein the one or more optical conduit distal in the distal end are rotatable within the support structure within the catheter.

With regard to independent claim 35, the elements of this claim are disclosed in paragraphs 13, 49 and 88 of the present application. Paragraph 88 of the present application discloses a catheter having “a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheromatous material distal to the tool. The tool 810 also includes a passage 818.” Paragraphs 13 and 49 further clarify that “open” lumens of the device can be used with optical coherence tomographic, or laser based imaging systems. Paragraphs 88-89 clarify that the catheter has a distal end structure 812 and one or more magnet members at the distal end. Paragraphs 7-8 indicate the magnet elements are oriented by changing the application of the externally applied magnetic field to cause the magnet members to align relative to the field.

Independent Claim 39

An atherectomy device comprising:

a catheter having a proximal and a distal end and a lumen therebetween;

a support structure in the lumen adjacent the distal end;

one or more optical conduits in the catheter, each having a distal end supported by the support structure;

one or more magnetic members disposed in the distal end of the catheter, whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field;

wherein the one or more magnet members are positioned within the catheter and are rotatable within the catheter.

With regard to independent claim 35, the elements of this claim are disclosed in paragraphs 13, 49 and 88 of the present application. Paragraph 88 of the present application discloses "a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheromatous material distal to the tool. The tool 810 also includes a passage 818." Paragraphs 13 and 49 further clarify that "open" lumens of the device can be used with optical coherence tomographic, or laser based imaging systems, or that lumens can be used with an optical fiber to perform laser induced fluorescence spectroscopy or optical low coherence reflectometry or optical coherence tomography. Paragraphs 88-89 clarify that the catheter has a distal end structure 812 and one or more magnet members at the distal end. Paragraphs 7-8 indicate the magnet elements are oriented by changing the application of the externally applied magnetic field to cause the magnet members to align relative to the field.

Dependent Claim 43

The device of claim 39, wherein at least one optical conduit is connected to an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located, and at least one optical conduit is connected to a remote optical laser energy source for conducting ablating laser energy to the distal end of the device.

With regard to claim 43, this claim clarifies that the atherectomy device comprises two optical conduits, at least one optical conduit that is connected to an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located, and at least one optical conduit that is connected to a remote optical laser energy source for conducting ablating laser energy to the distal end of the device. Paragraph 88 of the present application discloses "a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheromatous material distal to the tool. The tool 810 also includes a passage 818." Paragraphs 13 and 49 further clarify that "open" lumens of the device can be used with optical coherence tomographic, or laser based imaging systems.

GROUND FOR REJECTION TO BE REVIEWED ON APPEAL – UNDER 37 C.F.R. § 41.37(c)(1)(vi)

Appellants present the following issues for review:

1. Is the invention set forth in Claims 34-37, 39 and 44 anticipated by Ueda (U.S. Pat. No. 5,681,260)?
2. Is the invention set forth in Claims 38 and 40-42 obvious over Ueda (U.S. Pat. No. 5,681,260) in view of Conlan et al (U.S. Pat. No. 5,904,147) and further view of Goldenberg (U.S. Pat. No. 4,830,460)?
3. Is the invention set forth in Claim 43 obvious over Ueda (U.S. Pat. No. 5,681,260) in view of Conlan et al (U.S. Pat. No. 5,904,147)?

ARGUMENT – UNDER 37 C.F.R. § 41.37(c)(1)(vii)

1. 1st GROUND OF REJECTION ON APPEAL

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 1st ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

I. Ueda Fails To Disclose All The Claim Limitations

Claims 34, 35 and 39

Appellants submit that the reference Ueda relied upon for the above rejection now under appeal neither teaches nor suggests one or more optical conduits that are rotatable within the support structure within the catheter.

The Final Office Action states on Page 4 that the optical conduits can be rotated within the catheter device, since the conduits are loosely inserted. However, the Examiner's interpretation of "loosely inserted" is contrary to Ueda's teaching. Ueda discloses an insertable part 8 having a light guide 16 inserted through part 8 and light guide cable 14, and connected at the entrance end to connector 14A. This indicates that the light guide is secured at entrance end 14A, and would not be rotatable. While Ueda states that articulation frames 22 are connected rotatably with each other, this only pertains to the articulation frames, and does not support the Examiner's contention that Ueda's conduits 16/25 are also inherently rotatable. The disclosed rotation of Ueda's articulation frames relative to each other does not conclusively mean that the optical conduits must also rotate. The Appellant submits that Ueda neither teaches nor suggests one or more optical conduits that are rotatable within the support

structure in the catheter. As such, the Appellant submits that claims 34, 35 and 39 are not anticipated by Ueda.

Claims 36, 37 and 44

With regard to dependant claims 36-37 and 44, these claims depend from independent claims 35 and 39, which the Appellant believes to be allowable in view of the above remarks. As such, the Appellant submits that claims 36-37 and 44 are also allowable for at least these reasons.

2. 2nd GROUND OF REJECTION ON APPEAL

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 2nd ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

I. The References Fail To Disclose All The Claim Limitations

Claim 38

The Appellants submit that the reference Conlan relied upon for establishing the obviousness rejection now under appeal neither teaches nor suggests a laser ablation tool.

The Final Office Action states on page 5 that Conlan teaches the tip of the catheter as having an ablation instrument that is supplied with energy via an optical fiber (Conlan, column 10, lines 25-31). However, the Appellant submits that Conlan merely teaches an optical fiber for illumination. The cited portion of Conlan teaches a light pipe or optical fiber to conduct light to an emitting beacon, and positioning the device in a passage by such illumination. Conlan may teach

positioning the tip of an ablation catheter by such illumination, but Conlan fails to disclose a laser ablation tool or an optical conduit that conducts laser ablating energy to a laser ablation tool. Even assuming, arguendo, that Conlan teaches an ablation catheter that would inherently receive ablating energy, this does not make inherent laser ablation energy, since other ablating energy sources such as RF energy or electrical energy may also be used. There is no specific disclosure that the optical fiber disclosed in Conlan is supplied with ablating energy from a laser energy source. The Appellant submits that neither Conlan nor Ueda teach or suggest a laser ablation tool. As such, the Appellant submits that claim 38 is not obvious in view of the references for at least this reason.

Claim 41

The Appellants submit that the reference Conlan relied upon for establishing the obviousness rejection now under appeal neither teaches nor suggests one or more magnetic members disposed in the distal end of the catheter, wherein the one or more magnet members are comprised in a support structure.

Ueda discloses a hood 20 fitted to the tip, which hood is formed of a permanent magnet. (Ueda, column 8, lines 25-26). Conlan discloses a catheter having a balloon 26, and attaching a magnetic fragment to the balloon. (Conlan, column 8, lines 55-56). Accordingly, both Conlan and Ueda fail to disclose that the one or more magnets are comprised by a support structure, as claimed in

claim 40 and shown as 820 in Fig 26. As such, the Appellants submit that claim 41 is not obvious in view of the references for at least this reason.

Claims 40 and 42

With regard to dependant claims 40 and 42, these claims depend from independent claim 39, which the Appellant believes to be allowable in view of the above remarks. As such, the Appellant submits that claims 40 and 42 are also allowable for at least these reasons.

3. 2nd GROUND OF REJECTION ON APPEAL

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 2nd ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

I . The References Fail To Disclose All The Claim Limitations

Claim 43

The Appellants submit that the reference Conlan relied upon for establishing the obviousness rejection now under appeal neither teaches nor suggests an ablation instrument supplied with energy via an optical fiber. Page 5 of the Final Office Action contends that Conlan teaches the tip of the catheter as having an ablation instrument that is supplied with energy via an optical fiber (Conlan, column 10, lines 25-31). However, this cited portion of Conlan only teaches a light pipe or optical fiber to conduct light to an emitting beacon, and

then positioning the device in a passage by such illumination. Conlan may teach positioning the tip of an ablation catheter by such illumination, but Conlan fails to disclose a laser ablation tool or an optical conduit that conducts laser ablating energy to a laser ablation tool. Even assuming, arguendo, that Conlan teaches an ablation catheter that would inherently receive ablating energy (eg. - RF or electrical energy), there is no specific disclosure that an optical fiber is supplied with ablating energy from a laser energy source.

The Appellants submit that neither Ueda, or Conlan, disclose two optical conduits, where at least one optical conduit that is connected to an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located, and at least one optical conduit is connected to a remote optical laser energy source for conducting ablating laser energy to the distal end of the device. As such, the Appellant submits that claim 43 is not obvious in view of Ueda and Conlan.

CONCLUSION

Appellant respectfully submits that the Examiner has not shown that claims 34-44 are properly anticipated by Ueda (U.S. Pat. No. 5,681,260), or that claims 38 and 40-42, and claim 43 are obvious over Ueda (U.S. Pat. No. 5,681,260) in view of Conlan et al (U.S. Pat. No. 5,904,147). Accordingly, reversal of the rejections of Claims 34-44 are respectfully requested.

5 - 19 - 07

Respectfully submitted,



Kevin M. Pumm, Reg. No. 49,046
Harness, Dickey & Pierce, P.L.C.

7700 Bonhomme Avenue, Suite 400
St. Louis, MO 63105
(314) 726-7500

Date: 5-14-07

CLAIMS APPENDIX
UNDER 37 C.F.R. § 41.37(c)(1)(viii)

1 - 33.(Cancelled)

34. (previously presented) An atherectomy device comprising:
- a catheter having a proximal and a distal end and a lumen therebetween;
 - a support structure in the lumen adjacent the distal end;
 - one or more optical conduits in the catheter, each having a distal end supported by the support structure;
 - one or more magnetic members disposed in the distal end of the catheter whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field; and
- wherein the one or more optical conduit in the distal end are rotatable within the support structure.
35. (previously presented) An atherectomy device comprising:
- a catheter having a proximal and a distal end and a lumen therebetween;
 - a support structure in the lumen adjacent the distal end;
 - one or more optical conduits in the catheter, each having a distal end supported by the support structure;
 - one or more magnet members disposed in the distal end of the catheter that orient the distal end to align relative to an applied magnetic field, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field; and

wherein the one or more optical conduit distal in the distal end are rotatable within the support structure within the catheter.

36. (previously presented) The device of claim 35, wherein the support structure comprises the one or more magnetic members.
37. (previously presented) The device of claim 36, wherein the support structure comprises a sheath.
38. (previously presented) The device of claim 37, wherein the device comprises a laser ablation tool.
39. (previously presented) An atherectomy device comprising:
 - a catheter having a proximal and a distal end and a lumen therebetween;
 - a support structure in the lumen adjacent the distal end;
 - one or more optical conduits in the catheter, each having a distal end supported by the support structure;
 - one or more magnetic members disposed in the distal end of the catheter, whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field;
 - wherein the one or more magnet members are positioned within the catheter and are rotatable within the catheter.
40. (Previously Presented) The device of claim 39, further comprising an ablation member at the catheter distal end.
41. (Previously Presented) The device of claim 40, wherein the one or more magnet members are comprised by the support structure.
42. (Previously Presented) The device of claim 41, wherein the support structure comprises a passage for a guidewire.

- 43 (Previously Presented) The device of claim 39, wherein at least one optical conduit is connected to an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located, and at least one optical conduit is connected to a remote optical laser energy source for conducting ablating laser energy to the distal end of the device.
44. (Previously Presented) The device of claim 39 wherein at least one optical conduit comprises an optical fiber having a beveled distal end facing generally radially outwardly for imaging the vessel in which the device is located.

EVIDENCE APPENDIX UNDER 37 C.F.R. § 41.37(c)(1)(iX)

- A copy of the Office Action mailed November 13, 2006 placing the present application under final rejection is provided

RELATED PROCEEDINGS APPENDIX - UNDER 37 C.F.R. § 41.37(c)(1)(x)

NONE.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,018	02/05/2001	Roger N. Hastings	5236-000215	5479

7590

11/13/2006

Harness, Dickey & Pierce
Suite 400
7700 Bonhomme
St. Louis, MO 63105

EXAMINER

BRANDT, ADAM CURTIS

ART UNIT


PAPER NUMBER

3771

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

EV 844119685 11/13

 Office Action Summary	Application No. 09/777,018	Applicant(s) HASTINGS ET AL.	
	Examiner Adam Brandt	Art Unit 3771	

MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 34-37, 39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US 5681260).

Ueda et al. disclose a device comprising a catheter 8 having a proximal and a distal end and a lumen therebetween (Figure 28). A catheter is defined as "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway." (dictionary.com). Therefore, the catheter 8 of Ueda et al. reads on this definition. Ueda et al. continues to disclose a support structure 22/94/140 in the lumen adjacent the distal end. Ueda et al. also discloses one or more optical conduits 16/25 in the catheter 8, each having a distal end supported by the support structure 22/94/140 and one or more magnetic members (19/82/20/95) disposed in the distal end of the catheter 8. In addition, the distal end of the catheter 8 is oriented by one or more magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field from magnetic generator 11/31 (Abstract). Lastly, Ueda et al. teach one or more optical conduit 16/25 in the distal end is inherently capable of being rotated within a support structure 22/94/140. The support structure as stated can be broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the

optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41).

As for claim 35, the magnet members (19/82/20/95) disposed in the distal end of the catheter that orient the distal end to align relative to an applied magnetic field 11/31, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field (Abstract).

In regards to claims 36 and 37, Ueda et al. teach a support structure 140 comprising one or more magnetic members 142 (Figure 25). Ueda et al. continue to disclose a support structure comprising a sheath 84/85 (Figure 11).

As for claim 39, Ueda et al. disclose one or more magnetic members 142 disposed in the distal end of the catheter 8, whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field 11/31. In addition, the one or more magnet members 142 are positioned within the catheter 8 and are inherently capable of being rotatable within the catheter since the magnet is manually inserted into channel 140, therefore, the magnet is capable of being manually rotated in any direction.

As for claim 44, Ueda et al. discloses in figure 27 the device of claim 39 wherein at least one optical conduit comprises an optical fiber having a beveled distal end facing generally radially outwardly for imaging the Bessel in which the device is located (see column 18, ln. 9-10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Conlan et al. (US 5904147) and further in view of Goldenberg (US 4830460).

Ueda et al. disclose a vivisectioning forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including an optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

As for claim 42, Ueda et al. teach a support structure 94/140 comprising a passage for a guide wire. Goldenberg discloses a similar support structure in a sleeve 72 that explicitly teaches a passage for a guidewire 70 (column 13, lines 65-68). Therefore, it would have been obvious for a person having ordinary skill in the art at the time of the invention to advance a guidewire through this passage to ensure an optical fiber remains in alignment.

5. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Conlan et al.

Ueda et al. discloses in column 8, lines 1-24, an optical imaging system for acquiring an image of the interior circumference of a vessel in which the device is located and also discloses in column 7, lines 53-67, an optical conduit used to emit light on the insertable tip. Ueda fails to disclose a laser energy source for conducting ablating laser energy to the distal end of the device. Conlan teaches the tip of the catheter as having an ablation instrument (column 10, lines 25-31) that is supplied with energy via an optical fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the second optical conduit of Ueda to deliver laser energy to the ablating device of Conlan in order to minimize the effects of hemorrhaging by visual inspection via imaging system located in the first optical conduit.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

Art Unit: 3771

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 34-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 in view of Ueda et al.

The sheath in claims 7, 18, and 19 reads on a support structure of claim 1 of the instant application. An energy source in claims 1, 18, and 19 can be broadly interpreted as an optical conduit or vice versa. Lastly, the magnetically active element in claims 1 and 18-20 reads on the magnetic members in claim 1 of the instant application. As for the optical conduit or energy source as being rotatable, Ueda et al. teach one or more optical conduit 16/25 in the distal end as being inherently capable of rotation within a support structure 22/94/140. The support structure as stated can be broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of the claims of '026 with the optical conduit being rotatable in order to position an optical conduit at a desired position before or during insertion.

Art Unit: 3771

8. Claims 38 and 40-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 and Ueda et al. in view of Conlan et al., and further in view of Goldenberg.

Ueda et al. disclose a vivisecting forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including an optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention of the claims of '026 and Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

Response to Arguments

9. Applicant's arguments filed 8/03/2006 with respect to claims 34-43 have been fully considered but they are not persuasive.

In response to the Applicants arguments of claims 34, 35, and 39:

The Applicant argues that Ueda does not disclose a catheter device having magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field from a magnetic field generator (11/31/61). The Applicant further states that Ueda discloses a tip that is attracted by a magnetic force, which is moved towards a magnetic force generating part (31).

The Examiner notes that a magnetic force is a product of a magnetic field. Therefore, every magnetic field inherently has magnetic forces associated with it. Additionally, it is inherent that a magnet will align with the field by way of the force. Since the invention of Ueda discloses a tip that is attracted by a magnetic force which is generated at a remote location, it does in fact meet the claim limitation.

The Examiner fails to see how the example provided by the Applicant in the last paragraph of page 5 of the remarks relates to the argument. Ueda discloses a tip this movable in relation to the position of a magnet which the Examiner supposes is analogous to the Applicant's example of "a magnet held close above a compass causes the compass needle to be attracted up towards the magnet". The Examiner understands the Applicant's example as it applies to a magnet that is held above a conventional compass that lies flat on a table. The needle of the compass tries to escape its horizontal plane of movement in order to point towards the magnet. In other words, the needle has some positive angle of elevation from the horizontal plane because the needle is trying to point towards the magnet. The needle of the compass, which has its vertical movement restricted by a securing means (such as a pin) will thus align itself with the polarity of the magnet.

The Applicant's second example is of "a magnet rotated above a compass that causes the compass needle to rotate and align with the direction of the magnetic field of the rotating magnet". The example provided by the Applicant is interpreted by the Examiner as a conventional compass laying flat on a table so that the needle can move in the horizontal plane. A conventional 2-pole magnet is placed over top of the compass. When rotated the needle of the compass rotates with the magnet's position so that the needle is aligned with the orientation of the

magnet. The Examiner fails to how these examples clarify the arguments set forth in the Applicant's preceding paragraphs.

The Applicant recites that the disclosure teaches that a magnetic field is used to align the tip relative to the direction of the field and therefore, unlike Ueda, the claimed magnet members may be aligned in a desired direction other than towards the magnet by changing the magnetic field's direction. The Examiner notes that in paragraph 43, line 16-17, the Applicant discloses that magnetic force is used to align the tip. Magnetic forces are used to align the tip relative to the magnetic field so it will move in the proper direction. Ueda discloses a tip that utilizes magnetic forces to direct its movement. The Examiner believes that Ueda discloses the limitation set forth in the Applicants claims.

In response to the Applicants arguments of claims 38, and 40-43:

The arguments have been responded to above.

In response to the Applicants arguments towards the Double Patenting Rejection:

The arguments have been responded to above.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

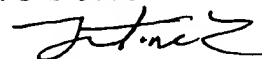
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB



Adam Brandt
Examiner
Art Unit 3771



JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

11/8/06